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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SCHLIENTZ, LEAH H

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

08/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/830,195	Applicant(s) BUISER ET AL.	
	Examiner Leah Schlientz	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-11,13,15,17,19-31,49-54 and 56-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-11,13,15,17,19-31,49-54 and 56-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 5/4/2009, in reply to the Office Action mailed 3/23/2009, is acknowledged and has been entered. Claims 1, 10, 13, 54 have been amended. Claims 5, 12, 14, 16, 18, 32-48 and 55 have been cancelled. Claims 60-63 are newly added. Claims 1-4, 6-11, 13, 15, 17, 19-31, 49-54 and 56-63 are pending and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive, for reasons set forth hereinbelow.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/21/2009 was filed after the mailing date of the Office Action on 3/23/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 4, 6-11, 13, 15, 17, 19- 26, 28- 31, 49-54 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen (US 6,530,943) and Greene (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), in further view of Mazzocchi (US 6,605,102), for reasons set forth in the previous Office Action.

Applicant argues on pages 9-11 of the Response that Jacobsen and Greene describe chains of joined beads or embolizing elements along a filament, and asserts that Jacobsen emphasizes the importance of joining beads having a central bore and formed of a material having a particular density and surface porosity. Applicant contends that the joined embolizing elements described in Greene are formed on a polymer with sufficient softness to be coaxially skewered along a carrier filament, or the embolizing elements are molded around the filament. Applicant argues that Smith describes porous beads having very specific pore structures formed by precipitation methods that require certain specific conditions; and that Smith fails to disclose how to form such particles having a central bore and density requirements emphasized by Jacobsen, or the softness to permit coaxial skewering along a filament in the manner disclosed in Greene. Applicant argues that the cited references alone or in combination do not render obvious joining beads of Smith according to the teachings of Greene or Jacobsen, nor do Greene or Jacobsen disclose or render obvious modification of particles produced in Smith to obtain the claimed compositions. Applicant argues that the Office does not assert a basis for one skilled in the art to identify those polymer particles (if any) disclosed in Smith that are suitable for preparing the devices in

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Jacobsen. Applicant further argues on pages 11-13 of the Response that in "in order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method," and that one skilled in the art cannot make the compositions in the rejected claims based on the cited prior art and the Examiner provides no basis to actually make the claimed connected porous particles. Applicant asserts that undue experimentation would be required to make and use the claimed connected particles based on the asserted combination of Jacobsen, Smith and Greene, And that the Office provides no explanation describe how to (1) place a central bore in each bead produced by Smith (2) select particles if any produced by Smith having the pore density and surface porosity requirements described by Jacobsen and/or (3) provide beads by the process of Smith having a softness adequate to permit joining particles with the filamentous carrier described by Greene.

This is not found to be persuasive. Jacobsen does not appear to teach a particular density as alleged by Applicant, and merely teaches that particles can be selected to have a density that are less than the density of blood, or can include metals to increase density, or one can select mixtures of polymer and metal (column 4, lines 28+). Smith teaches that asymmetric microporous beads often have density less than 1 g/cm³. Smith also teaches the option of loading high density material to the beads if desired. Blood has an average density of 1.06 g/cm³, therefore Smith's density can be less than that of blood, which is line with Jacobsen's teaching, or Smith can include metal to provide greater density if desired. With regard to Applicant's argument that Smith fails to disclose how to form particles having a "central bore" or the softness to

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permit "coaxial skewering" along a filament in the manner disclosed in Greene, Smith and Greene all teach overlapping polymer species (e.g. PVA or acrylics in Greene or ethylenevinyl alcohols or acrylics in Smith, among other polymers), and both teach porous beads or micropellets, therefore absent evidence to the contrary beads having the pore distribution set forth in Smith including overlapping polymer species as those of Greene would be capable of being skewered with a filament, which would represent a central bore.

Applicant argues on page 13-14 that Mazzocchi does not render obvious particles having a link having an aspect ratio of at least 0.001 and at most 1,000. Applicant argues that rejections on obviousness cannot be sustained with mere conclusory statements, and that the Office Action provides no basis in Jacobsen or elsewhere to make compositions with the particular links claimed.

This is not found to be persuasive. Green, Jacobsen and Mazzocchi all teach that the length of the chain is variable as desired. Green and Mazzochii both teach diameter of length. One of ordinary skill could readily optimize the length of the chain (thus directly varying aspect ratio) within the claimed range since Green, Jacobsen and Mazzochi all teach that length of chain/filament, etc. may be selected by the user. See Figures of Jacobsen, for example such as Figure 4. The width of the length is approximately 0.1 cm, and the length shown is approximately 5.5 cm. Such a width/length ratio shown would be within the widely varying claimed range of aspect ratio, especially since Jacobsen teaches that any length may be selected. It is further noted that the instant claims are composition claims, not method of making claims.

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Furthermore, see MPEP 2145 (III) regarding arguing that prior art devices are not physically combinable. “The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) (“[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.”); and *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973) (“Combining the teachings of references does not involve an ability to combine their specific structures.”).

Claims 1- 4, 6, 7, 15, 17, 19-23, 25-31, 49- 54 and 56-59 are rejected under 35 U.S.C. 103(a) as being obvious over Jacobsen *et al.* (US 6,530,934) in view of Lanphere *et al.* (US 2003/0185895), for reasons set forth in the previous Office Action.

Applicant argues on pages 15-17 of the Response that Jacobsen describes the importance of selecting material of beads to control the density of the string to have beads that are less than the density of blood and having a surface porosity to promote thrombogenicity after implantation. The beads are formed with a central bore through which a filament is threaded to maintain beads connected together with a chain.

Applicant argues that one skilled in the art would recognize that Jacobsen's method of making his particles would not be suitable for making particles chains that include Lanphere's particles.

This is not found to be persuasive. As set forth above, Jacobsen does not appear to teach a particular density as alleged by Applicant, and merely teaches that particles can be selected to have a density that are less than the density of blood, or can include metals to increase density, or one can select mixtures of polymer and metal (column 4, lines 28+). Lanphere teaches that the density of the particles is such that they are readily suspended in the carrier fluid such as a mixture of saline and contrast solution and remain suspended during delivery. In embodiments, the density is in about 1.1-1.4 g/cm³. Blood has an average density of 1.06 g/cm³, therefore Lanphere's density can be greater than that of blood, which is line with Jacobsen's teaching. With regard to Applicant's argument that Lanphere fails to disclose how to form particles having a "central bore," one could skewer the PVA particles, as in Greene, for example, as above. It is further noted that the instant claims are composition claims, not method of making claims. Furthermore, see MPEP 2145 (III) regarding arguing that prior art devices are not physically combinable. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."); and *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973)

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("Combining the teachings of references does not involve an ability to combine their specific structures.").

New Grounds for Rejection

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen (US 6,530,943) and Greene (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), as previously applied to claims 1, 2, 8, 9, 15, 17, 19-23, 25, 26, 28-31, 49-54 and 56-59.

With regard to claim 60, Greene discloses that carrier may be multistrand (paragraph 0099).

With regard to claims 61-62, Greene discloses PVA as both carrier and particle (paragraph 0093).

With regard to claim 63, Jacobsen discloses spherical beads, see Figures, and Smith discloses spherical beads.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §

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706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS